

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

COCKERELL
DERMATOPATHOLOGY, P.A. and
CLAY J. COCKERELL, M.D.,

Defendants.

Civil Action No.

COMPLAINT

1. The United States of America, on behalf of the United States Department of Defense, files this complaint against Defendants Cockerell Dermatopathology, P.A. (CDP) and Clay J. Cockerell, M.D. (Dr. Cockerell) to recover damages and civil penalties under the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, as well as the common law and equitable theories of payment by mistake and unjust enrichment.

I. PRELIMINARY STATEMENT

2. Dr. Clay Cockerell is the sole owner and president of CDP, a dermatopathology lab. From March 2015 through November 2016, Dr. Cockerell and CDP engaged in an illicit scheme with Progen Lab Systems, a lab management company, to submit fraudulent lab testing claims to the TRICARE healthcare program.

3. Progen used a network of commission-based marketers to generate lab referrals. But Progen was not a certified lab. It was not a registered healthcare provider. Progen's four principals had no experience running a clinical lab. And Progen did not

have the appropriate license, known as a CLIA license, necessary to submit lab claims to insurance programs—including federal healthcare programs.

4. To get around these problems and to avoid CLIA registration, Dr. Cockerell allowed Progen to use CDP’s CLIA license and provider identification number in exchange for a 20 percent cut of Progen’s net revenue. CDP and Progen commemorated their agreement in a Management Services and Operations Agreement (MSA) dated March 10, 2015.

5. Dr. Cockerell, CDP, and Progen knew that federal law—namely, the Anti-Kickback Statute (AKS)—prohibits any person from knowingly and willfully soliciting, paying, or receiving any remuneration meant to reward federal healthcare referrals. They realized their arrangement could implicate the AKS’s prohibitions since CDP would remit payment to Progen (for moneys received by CDP for lab claims submitted effectively on behalf of Progen), and Progen in turn would route patients to CDP. And so they excluded federal healthcare programs from the MSA altogether. CDP and Progen agreed not to provide lab services to any federal patients nor to accept any government receivables.

6. Shortly after signing the MSA, Dr. Cockerell learned that Progen was engaged in gross mismanagement. He discovered that Progen utilized suspect practices such as paying commissions to marketers and waiving patient copays. And he also learned that Progen was generating referrals to federal programs such as TRICARE.

7. As enrolled healthcare providers, Dr. Cockerell and CDP knew about the FCA. They knew they could not submit claims to federal healthcare programs, including

TRICARE, without regard to their truth or falsity. And they were confronted with multiple red flags indicating that Progen was engaged in misconduct and AKS violations. Nonetheless, and despite the express prohibition in the MSA, Dr. Cockerell allowed Progen to continue to use CDP's CLIA license to submit claims for payment to TRICARE. Payment for those claims went directly to CDP, which passed the money to Progen. And in return Dr. Cockerell and CDP expected 20 percent of the net proceeds.

8. CDP began submitting claims for Progen in May 2015. CDP submitted a couple claims to TRICARE and was paid approximately \$2,872 on the basis of those claims.

9. In June 2015, CDP submitted to TRICARE approximately 234 claims for payment for Progen's lab tests, and TRICARE paid CDP approximately \$278,903 for those claims. In July 2015, the Progen claims skyrocketed—CDP submitted approximately 581 claims, and TRICARE paid CDP approximately \$760,297.

10. Even though the MSA purported to exclude federal revenue from the arrangement, CDP transmitted the federal payments, including the TRICARE reimbursements, to Progen. And Dr. Cockerell and CDP made clear to Progen that they expected their 20 percent cut to include Progen's federal referrals as well.

11. On July 30, 2015, Maggie Kipp (CDP's CFO) warned Dr. Cockerell that CDP was risking FCA liability by accepting federal reimbursement for Progen's referrals. But Dr. Cockerell brushed off her concerns and allowed Progen to continue submitting claims to TRICARE using CDP's CLIA license and provider number.

12. In the following months, Progen paid CDP \$600,000 for its role in the scheme. Meanwhile, patient complaints began to mount against CDP as patients received bills for the fraudulent testing. Patients threatened to report CDP for fraud, and at least one person filed a complaint with the Texas Medical Board. In a December 28, 2015 email to Progen's principals, Dr. Cockerell complained: "At the end of the day, ultimately I am responsible and this puts me at risk like this."

13. Despite these myriad red flags, CDP continued to allow Progen to use its CLIA license and provider number to submit claims to federal healthcare programs, including TRICARE. From August 2015 through December 2015, CDP submitted approximately 8,354 claims to TRICARE for Progen's lab tests. TRICARE paid CDP approximately \$3,251,073 for those claims.

14. On January 12, 2016, CDP sent a retraction letter to TRICARE admitting \$923,606 in improper claims. CDP's letter attributed the claims to an "internal system issue" that led to the claims being "submitted in error." In reality, these claims related to two Progen marketers, Britt and Matthew Hawrylak. As part of their marketing scheme, TRICARE beneficiaries received Wal-Mart gift cards in exchange for urine samples, which were sent to Progen for lab tests. Progen then submitted claims for those lab tests to TRICARE using CDP's CLIA license and provider number. Both Britt and Matthew Hawrylak have since pleaded guilty to conspiracy to commit healthcare fraud in connection with this lab scheme. In its retraction letter to TRICARE, CDP admitted that these claims were improper and promised to refund TRICARE for all of these erroneous claims. But it did not.

15. From January 2016 through May 2016, CDP submitted approximately 1,425 more claims to TRICARE for Progen's lab tests. TRICARE paid CDP an additional \$436,141 for those claims.

16. On June 8, 2016, CBS Evening News aired a story about CDP titled "U.S. military members duped to help pull off insurance fraud."¹ CBS reported that patients received Wal-Mart gift cards in exchange for urine samples, and that CDP billed TRICARE for fraudulent and medically unnecessary lab tests using those samples. CDP told CBS that it was voluntarily refunding "significant amounts of money," but would not say how much.

17. On June 22, 2016, CDP sent another letter to TRICARE, this time admitting an additional \$3,272,530 in improper claims. These claims again related to the Hawrylaks and the Wal-Mart gift card scam. Together, CDP's two letters admitted that CDP had been paid almost \$4.2 million from TRICARE on improper claims.

18. CDP finally terminated the MSA with Progen in November 2016, around the time it learned it was under federal investigation. Three months later, CDP filed an arbitration claim against Progen and its principals. In the arbitration, CDP sought indemnification from Progen for the "millions of dollars" that it expected to have to repay to the government for the fraudulent TRICARE claims.

¹ <https://www.cbsnews.com/news/us-military-members-duped-to-help-pull-off-insurance-fraud/> (last visited on March 17, 2021).

19. On July 12, 2017, while the arbitration was pending, the U.S. Attorney's Office for the Northern District of Texas filed a criminal Felony Information against the Hawrylaks and two other individuals connected with the Wal-Mart gift card scam. All four pleaded guilty to conspiracy to commit healthcare fraud.

20. On December 12, 2018, Progen's four principals (among others) were indicted on healthcare fraud charges in the Northern District of Texas. As explained *infra*, the indictment relates to their involvement in the Rxpress compounding pharmacy. Progen's principals are alleged to have facilitated the payment of illegal kickbacks to marketers, or to have received kickbacks, for prescriptions for compound drugs that were submitted to federal healthcare programs such as TRICARE. One of those principals, Luke Zeutzius, has since pleaded guilty to conspiracy to defraud the United States and pay and receive kickbacks.

21. In March 2019, CDP settled its claims against Progen and its principals for \$3.485 million. Along with their settlement agreement, CDP and Progen executed a Memorandum of Understanding (MOU) explaining the purpose of the settlement payment. Dr. Cockerell and CDP specifically represented and warranted to Progen's principals that the \$3.485 million settlement amount would be used to repay TRICARE. Moreover, CDP represented and warranted that it would not try to persuade the government to recoup the fraudulent TRICARE claims from Progen or its principals.

22. But CDP and Dr. Cockerell chose to keep the \$3.485 million payment for themselves. Despite the representations in the MOU, they did not use the money to repay TRICARE. And when the government issued a civil investigative demand to CDP

seeking, *inter alia*, documents related to the settlement agreement (including, in particular, any memorandum of understanding), CDP produced the settlement agreement but did not produce or disclose the MOU.

23. Dr. Cockerell and CDP have refused to reimburse TRICARE for the admittedly false claims that they submitted, or even, at a minimum, the \$3.485 million from the settlement with Progen they agreed to use to pay back the government. The government seeks to recover the moneys paid to CDP on the basis of the fraudulent TRICARE claims that CDP has previously admitted were improper. As described in greater detail below, CDP and Dr. Cockerell, at a minimum, acted recklessly as to the truth or falsity of the TRICARE claims generated by Progen and submitted for payment under CDP's provider number and CLIA license. In the alternative, the government seeks to recover at least the \$3,485,000 Progen payment that Dr. Cockerell and CDP concealed and retained.

II. JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 & 1345, and supplemental jurisdiction over the common law and equitable causes of action under 28 U.S.C. § 1337(a).

25. This Court may exercise personal jurisdiction over each Defendant pursuant to 31 U.S.C. §§ 3732(a) & (b). Jurisdiction is proper over each Defendant because acts committed in violation of the FCA by the Defendants occurred in the Northern District of Texas, and because one or more of the Defendants can be found in, resides in, and/or transacts business in the Northern District of Texas.

26. Venue is proper in the Northern District of Texas under 31 U.S.C. § 3732, 28 U.S.C. §§ 1391(b)-(c), and 28 U.S.C. § 1395 because Defendants reside in and/or transact business in the Northern District of Texas.

III. PARTIES

27. Plaintiff United States brings this action on behalf of the United States Department of Defense (DOD), specifically the Defense Health Agency (DHA), which administers the TRICARE program.

28. Defendant Cockerell Dermatopathology, P.A. is a professional association incorporated in the state of Texas. Its principal address is 2110 Research Row, Suite 100, Dallas, Texas 75235-2520. It may be served through its registered agent, Tom M. Dees, 1445 Ross Avenue, Suite 2400, Dallas, Texas 75202-2758.

29. Defendant Clay J. Cockerell is a physician. He is the owner and President of CDP. Dr. Cockerell may be served at his place of residence, 3725 Cragmont Avenue, Highland Park, Texas 75205.

IV. LABORATORY TEST OVERVIEW

A. Laboratory Services

30. “Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or

assessment of a medical condition.” Medicare Benefit Policy Manual (MBPM), Pub. 100-02, Ch. 15, § 80.1.²

31. Physicians and medical providers utilize various kinds of laboratory testing in their assessments of patients. At issue in this case are toxicology and pharmacogenomic tests.

32. Toxicology testing is typically used to detect recent drug use by a patient. Toxicology tests are predominantly performed on a patient’s urine.

33. Pharmacogenomic (PG) testing tests for specific genetic variations that may affect the way that individuals react to certain medications. PG tests often involve blood or saliva specimens.

B. Regulatory Requirements for Laboratory Services

34. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, as set forth at 42 C.F.R. Part 493.

35. Under CLIA, CMS oversees all laboratory testing services. Certain simple tests are CLIA-waived—that is, they are categorized as simple laboratory procedures that have an insignificant risk of an erroneous result or pose no risk of harm to the patient if the test is performed incorrectly. 43 C.F.R. § 493.15(b). To perform CLIA-waived tests, physicians need to enroll in CLIA and obtain a waiver. 42 C.F.R. § 493.35. To perform

² Available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf> (last visited on November 19, 2020).

moderate or high-complexity laboratory tests, physician practices and laboratories are generally required to obtain a CLIA certification. 42 C.F.R. §§ 493.20, 493.25.

36. CDP received a Certificate of Registration from CLIA dated April 15, 2013. CDP's CLIA number is 45D2057348. CDP's CLIA license allowed it to perform moderate or high-complexity tests and submit claims for reimbursement to federal healthcare programs.

37. The lab services at issue in this case required a CLIA license. They could not be billed to federal healthcare programs without a CLIA license.

38. Laboratories such as CDP have a ““legal duty to ensure that [they are] not submitting false or incorrect claims to Government . . . payors.”” *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 165 (D.D.C. 2017) (quoting Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076, 45,077 (Aug. 24, 1998)). As part of that duty, “laboratories should ensure that they do not submit claims for medically unnecessary tests by, *inter alia*, communicating with physicians regarding medical necessity, maintaining documentation of medical necessity, constructing requisition forms to promote conscious ordering of tests by physicians, and reviewing coding.” *Id.* (citing 63 Fed. Reg. at 45,079-80).

V. THE TRICARE PROGRAM

39. TRICARE, formerly known as Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), is a Department of Defense program that helps pay for covered civilian health care obtained by certain military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10 U.S.C. §§ 1079,

1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims. Since 2013, the TRICARE program has been managed by DHA, the Defense Health Agency, a component of DOD.

40. TRICARE contracts with Humana Government Business, Inc., d/b/a Humana Military, to administer the TRICARE program, including the processing and payment of claims for reimbursement of physician and ancillary services from TRICARE.

41. TRICARE covers only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (in duration or intensity) the level of care which is needed to provide safe, adequate, and appropriate diagnosis and treatments.

See 32 C.F.R. § 199.4(a)(1)(i) and applicable definitions at 32 C.F.R. § 199.2.

42. Providers seeking payment from TRICARE have a duty to familiarize themselves with, and comply with, the program requirements to avoid fraud and abuse. 32 C.F.R. § 199.9(a)(4). TRICARE specifically identifies commission and kickback arrangements as examples of fraud. *Id.* § 199.9(c)(12).

43. TRICARE regulations provide that TRICARE may deny payment in “abuse situations.” 32 C.F.R. § 199.9(b). To avoid abuse situations, providers are obligated to

provide services and supplies under TRICARE that are: “Furnished at the appropriate level and only when and to the extent medically necessary . . .; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be required under this part . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care.” *Id.* The regulations expressly include as a possible example of abuse: “a battery of diagnostic tests are given when, based on the diagnosis, fewer tests were needed.” *Id.*

44. Some TRICARE services require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. § 199.4(f). A provider of services cannot, as a matter of law, waive these co-pay or deductible requirements. *Id.* § 199.4(f)(9). TRICARE regulations also identify the routine waiver of patient co-pays or deductibles as an example of abuse. *Id.* § 199.9(b)(1).

45. Fraud or abuse by a provider may result in the provider’s suspension or exclusion from the TRICARE program. 32 C.F.R. § 199.9(f).

A. Requirements for Payment

46. For a healthcare provider to seek reimbursement from TRICARE, the provider must obtain a National Provider Identifier (NPI) from the Centers for Medicare & Medicaid Services (CMS). CDP’s NPI number is 1528300837. The provider must also submit an enrollment application to participate in TRICARE.

1. CDP’s enrollment in TRICARE.

47. In August 2013, CDP entered into an “Ancillary Service Agreement” with Humana Military to become a participating provider in the TRICARE program. As part

of that agreement, CDP “agree[d] to provide health care services for Beneficiaries in accordance with the TRICARE program regulations, policies and procedures.” CDP further “agree[d] to abide by all quality assurance, utilization management, grievance, appeals, rules, regulations and other policies and procedures including claims submission policies and TRICARE program payment methodologies applicable to the TRICARE program.”

48. The Ancillary Service Agreement further required CDP to collect any patient copayments applicable to any covered services provided by CDP.

49. The Ancillary Service Agreement further required CDP to comply with all applicable federal laws and regulations, as shown below:

23. **Compliance with Laws and Regulatory Requirements:** Provider agrees to be bound by and comply with the provisions of all applicable state and federal laws and regulations. If Provider violates any of the provisions of applicable state and federal laws or commits any act or engages in conduct for which its license is revoked or suspended by the State in which the Provider is licensed, or is otherwise disciplined by any regulatory or accrediting organization, or in the event Provider fails to maintain participation in the Medicare or TRICARE program, HM may terminate this Agreement as specified in **Attachment D**.

50. Mark Faselle, CDP’s Vice President of Health Plans, executed the Ancillary Service Agreement on CDP’s behalf on August 12, 2013.

2. Claim submission process.

51. To obtain reimbursement from federal healthcare programs, providers submit a claim form, which is often done electronically.

52. For claims to TRICARE, providers submit CMS Form 1500 and/or its electronic equivalent, known as the 837P form, which contain the following certifications:

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license #, or SSN) of the primary individual rendering each service is reported in the designated section.

53. Because it is not feasible for the TRICARE program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers: (1) to comply with TRICARE requirements; and (2) to submit truthful and accurate claims and certifications.

3. Dr. Cockerell's enrollment in Medicare confirms his understanding of the AKS and the FCA—and his obligation to submit truthful and accurate claims to federal healthcare programs.

54. In order to participate in Medicare, providers must periodically submit an application. The application process for labs requires the submission of the Medicare Enrollment Application on form CMS-855B (Form 855B).

55. On May 1, 2013, CDP completed a Form 855B for enrollment in the Medicare program. Section 15 of that form required Dr. Cockerell to certify:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-

kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

56. The Form 855B further required Dr. Cockerell to certify: "I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

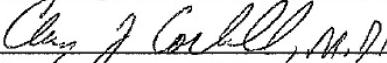
57. Dr. Cockerell signed the certification statement on behalf of CDP on May 1, 2013, as shown below:

| Authorized Official's Information and Signature | | | |
|---|-----------------------------|-----------|------------------------------------|
| First Name | Middle Initial | Last Name | Suffix (e.g., Jr., Sr.) |
| Clay | J | Cockerell | M.D. |
| Telephone Number (855) 754-6728 | Title/Position President | | Date Signed (mm/dd/yyyy) 5-1-13 |
| Authorized Official Signature (First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.) <i>Clay J Cockerell, M.D.</i> (blue ink preferred) | | | |

58. In addition to CDP's Medicare enrollment, Dr. Cockerell enrolled in Medicare as a participating physician. This application process requires the submission of the Medicare Enrollment Application on form CMS-855I (Form 855I).

59. On September 15, 2014, Dr. Cockerell completed a Form 855I to revalidate his enrollment in the Medicare program. Section 15 of that form required Dr. Cockerell to certify that he would abide by Medicare laws and regulations, including specifically the AKS. It also required Dr. Cockerell to certify: "I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

60. Dr. Cockerell signed the certification statement on September 15, 2014, as shown below:

| SECTION 15: CERTIFICATION STATEMENT (Continued) | | | |
|--|----------------|-----------|---------------------------------------|
| First Name | Middle Initial | Last Name | M.D., D.O., etc. |
| Clay | J. | Cockerell | M.D. |
| Practitioner Signature (First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)  | | | Date Signed (mm/dd/yyyy) 9-15-2014 |
| All signatures must be original and signed in ink (blue ink preferred). Applications with signatures deemed not original will not be processed. Stamped, faxed or copied signatures will not be accepted. | | | |

61. In addition to the TRICARE regulations and CLIA requirements discussed above, when Dr. Cockerell and CDP enrolled in Medicare, they were required to certify that they would comply with the AKS, that compliance with the AKS was a prerequisite for the submission of claims to federal healthcare programs, and that they would not submit claims to Medicare with deliberate ignorance or reckless disregard of their truth or falsity.

62. Moreover, Dr. Cockerell's certifications in CDP's Form 855B were a precondition for CDP and Dr. Cockerell to submit claims for payment to TRICARE. To enroll in TRICARE, CDP was required to have properly enrolled in Medicare and to have made these certifications. CDP's Ancillary Service Agreement with Humana Military required that CDP have "full participation status under Medicare" in order to be a TRICARE-enrolled provider.

VI. THE LAW

A. The False Claims Act

63. The FCA provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States government. 31 U.S.C. § 3729(a)(1).

64. The FCA establishes liability to the United States for any individual or entity that: “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1)(A); “knowingly makes, uses, or causes to be made or used, as false record or statement material to a false or fraudulent claim,” *id.* § 3729(a)(1)(B); or “conspires to commit a violation of subparagraph (A) [or] (B),” *id.* § 3729(a)(1)(C).

65. The FCA also establishes liability for reverse false claims, that is, for any individual or entity that “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” *Id.* § 3729(a)(1)(G).

66. To show that an individual or entity acted “knowingly” for purposes of the FCA, the United States must establish that such individual or entity: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or, (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

B. The Anti-Kickback Statute (AKS)

67. The AKS prohibits any individual or entity from soliciting, receiving, offering, or paying any remuneration to induce or reward any person for referring, recommending, or arranging for the purchase of any item or service for which payment may be made under a “federal health care program.” 42 U.S.C. § 1320a-7b(b).

68. To protect federal healthcare programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. The AKS makes it illegal for an individual or entity to knowingly and willfully:

[O]ffer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2).

69. This legal prohibition against using any kind of remuneration to induce patient referrals arose out of congressional concern that such kickbacks would result in goods or services being provided due to the economic self-interest of the parties, rather than based on an unbiased assessment of the patient’s medical needs. As the HHS, Office of Inspector General (HHS-OIG) has explained, the AKS “seeks to ensure that referrals will be based on sound medical judgment and that health care professionals will

compete for business based on quality and convenience, instead of paying for referrals.” OIG Advisory Opinion No. 12-06, OIG at p. 7 (May 25, 2012), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-06.pdf>; *see also* OIG Advisory Opinion No. 98-16, OIG (Nov. 3, 1998), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_16.htm (“One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals by providers who may be unduly influenced by financial incentives. The statute seeks to ensure that referrals will be based on sound medical judgment and that providers will compete for business based on quality and convenience, instead of paying for it.”).

70. A claim for reimbursement from a federal health care program for items or services resulting from a violation of the AKS “constitutes a false or fraudulent claim” under the FCA. 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal healthcare programs that result from violations of the AKS are *per se* false or fraudulent within the meaning of 31 U.S.C. § 3729(a)(1)(A)-(B). *See United States v. Medoc Health Servs., LLC*, 470 F. Supp. 3d 638, 655 (N.D. Tex. 2020). Accordingly, a person violates the FCA when he or she knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

71. Specific intent is not required to establish a violation of the AKS. *See* 42 U.S.C. § 1320a-7b(h) (“With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”).

72. The AKS has a safe harbor provision for “personal services and management contracts.” 42 C.F.R. § 1001.952(d). The personal services safe harbor

provides that, for purposes of the AKS, “remuneration” does not include any payments made as long as seven specific standards are met. *Id.* For example, the aggregate compensation paid must be set in advance, and payments cannot take into account the volume or value of any federal referrals. *Id.* § 1001.952(d)(5); *see also Medoc*, 470 F. Supp. 3d at 653.

73. The AKS also exempts from its purview “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” 42 U.S.C. § 1320a-7b(b)(3)(B). This provision may be referred to as the “bona fide employee” exception or safe harbor. Assessing whether an employment relationship is “bona fide” requires an assessment of multiple factors, such as the hiring party’s control over work hours. *See Medoc*, 470 F. Supp. 3d at 651-52.

VII. BACKGROUND

A. CDP, Rxpress, and Progen.

74. Dr. Cockerell opened CDP in or around June 2013. CDP’s specialty is dermatopathology, a field that focuses on the study of cutaneous diseases at a microscopic level. Dermatopathology often involves analysis of skin samples or biopsies using microscopes.

75. Before its arrangement with Progen, CDP did not perform PG or toxicology testing. And TRICARE was not a large portion of CDP’s business. For the year 2014, for example, CDP received only \$219,589 for claims CDP submitted to TRICARE.

76. Scott Schuster and Dustin Rall were owners and members of the Board of Directors of the Medicine Store Pharmacy, Inc. d/b/a Rxpress Pharmacy (Rxpress) in Fort Worth, Texas. Luke Zeutzius and Quintan Cockerell (Quintan) were marketers for Rxpress. Quintan is Dr. Cockerell's nephew.

77. Schuster, Rall, Zeutzius, and Quintan were not physicians. They were not registered healthcare providers. Their experience in the healthcare industry involved marketing.

78. Rxpress used a network of marketers to generate referrals for expensive "compound" medications, such as pain creams. Rxpress paid the marketers commissions for the referrals they generated. Schuster, Rall, Zeutzius, and Quintan sought out TRICARE referrals because they had high reimbursements.

79. By October 2014, as TRICARE faced skyrocketing costs for compound drugs, the Government Accountability Office recommended that TRICARE revise its payment practices to align with applicable regulations.³ In March 2015, TRICARE announced a new screening process, beginning on May 1, 2015, to ensure that compound drugs prescribed to TRICARE beneficiaries were safe, effective, and medically necessary. TRICARE paid far fewer claims for compound drugs after implementing these changes.

³ See GAO-15-64 (COMPOUNDED DRUGS: TRICARE's Payment Practices Should Be More Consistent with Regulations) (Oct. 2, 2014), available at <https://www.gao.gov/products/GAO-15-64> (last visited on March 17, 2021).

80. As compound drugs faced more and more scrutiny, Schuster, Rall, Zeutzius, and Quintan looked towards toxicology and PG tests as a potential source of revenue. Schuster, Rall, Zeutzius, and Quintan had never owned, managed, or operated a clinical laboratory.

81. On or around December 9, 2014, Schuster, Rall, Zeutzius, and Quintan formed Progen Lab Systems, LLC (Progen). Progen was incorporated in the state of Texas. It did not have a CLIA license or NPI number.

1. The Rxpress criminal proceeding.

82. On December 12, 2018, Schuster, Rall, Zeutzius, and Quintan (among others) were indicted on healthcare fraud charges in the Northern District of Texas. *United States v. Hall, et al.*, No. 3:18-cr-623-S (N.D. Tex.) (Dkt. No. 1). Schuster and Rall are alleged to have facilitated the payment of illegal kickbacks and bribes to marketers, including Quintan and Zeutzius, in exchange for prescriptions for compound drugs that were submitted to federal healthcare programs, including TRICARE.

83. On December 20, 2019, Zeutzius pleaded guilty to one count of conspiracy to defraud the United States and pay and receive kickbacks. (*Hall* Dkt. No. 200.) In his Factual Resume, Zeutzius admitted that he knowingly and willfully conspired and agreed with Schuster, Rall, Quintan, and others to defraud the United States, in particular the TRICARE program, and to knowingly and willfully solicit and receive kickbacks and bribes in exchange for TRICARE referrals. (*Hall* Dkt. No. 202.) Specifically, Zeutzius admitted that he received illegal kickbacks disguised as W-2 wages in exchange for prescriptions payable by federal healthcare programs. According to his Factual Resume,

from around May 2014 through around September 2016, Zeutzius received illegal kickbacks in the amount of \$4.5 million. Zeutzius further admitted that he shared those illegal kickbacks with Schuster and Rall.

84. Quintan is accused of receiving approximately \$2.4 million in illegal kickbacks and bribes from around May 2014 through around September 2016. According to the government's Superseding Indictment, to conceal the illegal kickbacks and bribes, Quintan "directed Person A [his wife] to complete paperwork and accept payments as a purported W-2 'employee' of Xpress Compounding on his behalf." (*Hall* Dkt. No. 229.)

85. Progen's business model was essentially the same as the Rxpress business model. Progen's principals used their network of marketers to generate referrals for clinical lab tests, and they paid the marketers commissions on the referrals they generated. As with the compounds, they sought out TRICARE patients because TRICARE offered high reimbursements.

B. Dr. Cockerell explores a lab venture with Progen.

86. Dr. Cockerell lived an expensive lifestyle. He owned a winery in Napa Valley (Coquerel Wines) that he could not afford. He owned two houses in Dallas, plus another home in Colorado. He was the partial owner of a private plane. Dr. Cockerell began to look for another source of revenue to supplement the income he received from CDP's dermatopathology business.

87. On November 10, 2014, Dr. Cockerell emailed Schuster and Quintan about the possibility of forming a genomics lab. Dr. Cockerell also mentioned Rxpress's

marketing strategy, noting that CDP was interested in working with them to market to physicians who performed skin biopsies. In other words, Dr. Cockerell knew from the beginning that his prospective business partners relied on marketers to generate referrals. While marketers are not problematic *per se*, certain marketing practices—such as paying commissions on federal referrals or waiving patient copays—can violate the AKS and FCA.

88. On December 8, 2014, Quintan emailed Schuster, Rall, Dr. Cockerell, and others a list of topics related to forming a new lab, including “CLIA expectations for new lab. Timetable and requirements etc.” Dr. Cockerell responded that the lab could use CDP’s CLIA license, as shown in the excerpt below:

From: Clay J. Cockerell, MD
Sent: Monday, December 8, 2014 6:54 PM CST
To: Quintan Cockerell
Subject: Re: Topics for Monday Meeting with Tootie

I won't be able to be there in person. Maybe by phone. Good list and I'll review.
9 month wait to get clia number. We have already so we can use ours.

89. Progen had not even been formed at this time, and yet Dr. Cockerell offered Quintan and his colleagues the use of CDP’s CLIA license.

90. In a separate email to Quintan dated December 8, 2014, Dr. Cockerell referenced keeping the new lab “under the radar screen.”

91. On January 21, 2015, Quintan emailed Dr. Cockerell and Brand McCarley (CDP Vice President of Sales and Marketing) about “marketing” for the lab venture. As

shown in the excerpt below, Quintan noted that one physician (Dr. Alec Tisdall)⁴ was ready to start sending samples to CDP. However, Quintan acknowledged that because federal healthcare programs would be involved, any marketing agreement would need to satisfy the services safe harbor to the AKS:

From: Quintan Cockerell
Sent: Wednesday, January 21, 2015 9:07 AM CST
To: Brand McCarley; Clay J. Cockerell, MD
Subject: Marketing

Brand
Tisdall is ready to start sending

We need some type of reimbursement numbers and marketing agreement

Probably need to get with Bill Meier about the agreement. There are limitations on how and what you pay a contractor when medicare is involved. Needs to be within the personal services safe harbors.

92. On February 9, 2015, Dr. Cockerell emailed Quintan asking about the status of the “ProGen agreement.” Dr. Cockerell noted that “[w]e also need to look at it from the standpoint of keeping it separate from CDP and our other entities so there could be no way we could be sued if ProGen was sued.”

C. The Management Services and Operations Agreement (MSA).

93. On March 10, 2015, CDP and Progen executed a “Management Services and Operations Agreement.” The MSA provided that Progen would acquire space, equipment, personnel, and supplies for CDP’s toxicology and genomic testing. Progen would also perform the toxicology and genomic tests for CDP. As part of the agreement,

⁴ Dr. Tisdall had been a referring physician to Rxpress. His PG and toxicology referrals ended up generating over \$500,000 in reimbursement from Medicare to CDP for the year 2015.

CDP authorized Progen to use CDP's "name and provider number(s)" to bill patients and payors for these lab services.

94. The MSA identified Progen as the "Manager," and CDP as the "Practice Operator." Under the MSA, CDP was required to ensure that it "compl[ied] with all Laws, including the Clinical laboratory (*sic*) Improvement Amendments, and maintain[ed] such licenses and accreditations as are necessary for the provision of clinical laboratory and other health care services by the Lab and the Payor Contracts."

95. Per the MSA, Progen would receive 80 percent of the net revenues for the laboratory services, and CDP would keep the remaining 20 percent.

96. The MSA did not comply with the personal services safe harbor of the AKS—the aggregate compensation from CDP to Progen was not set in advance, and it took into account the value of the laboratory services provided by Progen. And so CDP and Progen attempted to circumvent the AKS by carving out federal healthcare programs services and revenue from the arrangement, as shown in the excerpt below:

2.7 No Governmental Payors. Each party hereby agrees and acknowledges that it is the intent of the parties hereunder that no services shall be provided by the Lab that may result in any Government Receivables. The Practice Operator and Manager will not perform any services in the Lab for any patients enrolled in Medicare, Medicaid, or any other federal or state healthcare programs, including Medicare Part D or Medicaid Managed Care Plans or otherwise eligible to submit claims under any of those programs.

97. Per the terms of the MSA, CDP—the Practice Operator—was not supposed to provide testing services to federal healthcare beneficiaries as part of its arrangement with Progen. And it would not accept reimbursement from federal healthcare programs for Progen's referrals.

98. The MSA also included an indemnification provision whereby Progen agreed to indemnify and hold CDP harmless for any liabilities caused by Progen's negligence or misconduct.

99. Quintan signed the MSA on behalf of Progen. Dr. Cockerell signed the MSA on behalf of CDP.

100. For its lab space, Progen leased from CDP a separate suite within CDP's office building.

101. Before the MSA was signed, on or around February 26, 2015, CDP submitted an application to CMS to add Toxicology to its existing CLIA certificate. CMS-CLIA added Toxicology to CDP's CLIA certificate on May 13, 2015. CDP did not inform CMS-CLIA that a separate corporate entity (Progen) would actually be performing the toxicology lab tests.

102. After the MSA was executed, Progen's principals informed their marketing network that, as with compound drugs, they could make money from PG and toxicology referrals. To facilitate referrals, Progen prepared requisition forms for their lab tests. These requisition forms had a multitude of clinical laboratory tests, as well as the choice of a "Comprehensive Panel." The requisition forms had an "Xpress Laboratories, Inc." header (another name used by Progen), but the samples went to CDP for testing (i.e. the Progen lab that used CDP's name, NPI, and CLIA license with Dr. Cockerell's authorization). Insurance programs paid CDP for the claims, and patients received "Explanation of Benefits" statements listing CDP as the provider of the services.

103. With these requisition forms, Progen's marketers began to generate PG and toxicology referrals from their network of physicians.

104. Notwithstanding the federal carve-out in the MSA, Progen and its marketers sought referrals to federal healthcare programs such as TRICARE. And despite the carve-out, CDP and Dr. Cockerell knowingly allowed Progen to use CDP's CLIA license and NPI number to submit the claims to federal healthcare programs, including TRICARE. Reimbursement from these federal healthcare programs went directly to CDP.

105. A substantial portion of CDP's federal referrals came from the ADAR Group, described below. The ADAR Group was part of a scheme to generate lab referrals from soldiers or their family members stationed near Fort Hood.

D. The ADAR Group.

106. Prolixus Financial, LLC, d/b/a ADAR Group, LLC, was an addiction recovery service doing business at 1003 W. 10th Street, Killeen, Texas. ADAR stands for Alcoholism & Drug Addiction Recovery.

107. Erik Bugen was an owner and managing partner of ADAR Group.

108. Jody Sheffield was the operations manager of ADAR Group.

109. Matthew Hawrylak and Britt Hawrylak started working as sales reps for Rxpress in 2014. After Progen was formed, the Hawrylaks also became marketers for Progen. As described below, the Hawrylaks used the ADAR Group to generate lab referrals for Progen.

110. As an Rxpress sales rep, Britt Hawrylak received 35 percent commissions on the prescriptions that he generated for Rxpress. He also recruited sub-representatives to work under him. Britt would pay the sub-reps a portion of the commissions he received from their prescriptions, and Britt would keep the rest. Matt Hawrylak worked as a subrep under Britt.

111. One way that the Rxpress sales reps generated referrals was by paying doctors. For example, according to Matt Hawrylak, one mechanism to pay doctors was through the MSO (Medical Services Organization) model. Doctors would do sham “surveys” or “studies” on patients, discuss the “studies” at board meetings, and then split the commissions at the meetings. According to Matt Hawrylak, the payments to the doctors for prescriptions were disguised as payments for the “study.”

112. But other methods of payment were less discreet. According to Matt Hawrylak, certain physicians simply took direct payments for their prescriptions.

113. With the ADAR Group, the Hawrylaks implemented a marketing scheme similar to Rxpress.

114. In or about May 2015, Britt and Matthew Hawrylak approached Bugen about using the ADAR Group for outpatient toxicology testing. On June 3, 2015, Bugen and Sheffield leased office space in Killeen to set up a urine and saliva collection site.

115. As part of their scheme, the ADAR Group collected urine and saliva samples from TRICARE beneficiaries in exchange for gift cards. The samples were sent to Progen and billed to TRICARE for medically unnecessary toxicology and DNA cancer screening tests using CDP’s CLIA license and NPI number. TRICARE remitted payment

for these services to CDP, which then paid Progen. Progen, in turn, paid marketing fees—commissions—to the Hawrylaks. The Hawrylaks shared some of their commissions with Bugen and Sheffield to continue to flow of referrals.

116. Britt and Matthew Hawrylak provided the ADAR Group with \$10,000 per week to finance, among other things, the purchase of \$50 Wal-Mart gift cards to induce TRICARE beneficiaries to provide urine and saliva samples. They also provided funds to Bugen and Sheffield in order to pay doctors to sign test forms.

117. Ultimately, Bugen obtained signature stamps from the doctors to eliminate the need to meet with them. Sheffield and ADAR Group employees stamped the doctors' signatures on the testing forms. Beneficiaries did not see the doctors before obtaining the testing, did not receive test results, and did not know the purpose of their samples.

118. On July 12, 2017, the U.S. Attorney's Office for the Northern District of Texas filed a criminal Felony Information against Erik Bugen, Jody Sheffield, Matthew Hawrylak, and Britt Hawrylak. *See United States v. Bugen et al.*, No. 3:17-CR-370-D (N.D. Tex) (Dkt. No. 1). All four defendants pleaded guilty to conspiracy to commit healthcare fraud.

119. Sheffield admitted in his Factual Resume that he and Erik Bugen induced TRICARE beneficiaries to provide urine and saliva samples with \$50 Wal-Mart gift cards. Sheffield further admitted that he, Bugen, and the Hawrylaks also paid monthly fees to doctors to sign the Progen lab requisition forms. According to Sheffield, Bugen later obtained signature stamps from the doctors, and Sheffield and other ADAR Group employees stamped the requisition forms.

120. The ADAR Group's doctors included Dr. Vinay Parameswara, Dr. Sekhar Rao, Dr. Yun Kim, Dr. Sakshi Malhotra, and Dr. Alex Salazar.

121. According to Bugen, Dr. Rao was paid a fee of \$6,000 to \$8,000 per month, and he would sign Progen's lab requisition forms. On occasion, Dr. Rao would come to Bugen's residence to sign the forms. Eventually the ADAR Group switched to a stamp of Dr. Rao's signature, allowing the clinic to order tests without needing Dr. Rao to sign the forms. As will be detailed below, CDP caused these claims to be submitted to TRICARE by allowing Progen to submit them using CDP's CLIA license and NPI number. And TRICARE paid CDP directly for these fraudulent tests.

122. As an illustration, one of Progen's requisition forms is excerpted below. This form was used to order comprehensive panels of toxicology tests for TRICARE beneficiary J.M. on June 6, 2015. Dr. Rao signed the form, and the ADAR Group sent the urine sample and requisition form to Progen for testing:

| PRESCRIBED MEDICATIONS & TEST SELECTION | | |
|--|--|---|
| <input type="checkbox"/> Currently prescribed medications | <input type="checkbox"/> Medications to be analyzed (selecting drug class will analyze all drugs listed) | |
| LC/MS Confirmation | | |
| <input checked="" type="checkbox"/> OPIOIDS & OPIATES <input type="checkbox"/> MORPHINE <input type="checkbox"/> CODEINE <input type="checkbox"/> HYDROCODONE <input type="checkbox"/> BUPRENORPHINE <input type="checkbox"/> OXYCODONE <input type="checkbox"/> NALTREXONE <input type="checkbox"/> MEPERIDINE <input type="checkbox"/> FENTANYL <input type="checkbox"/> TRAMADOL <input type="checkbox"/> TAPENTadol <input type="checkbox"/> METHADONE <input type="checkbox"/> EDDP | <input checked="" type="checkbox"/> BENZODIAZEPINES <input type="checkbox"/> ALPRAZOLAM <input type="checkbox"/> CLONAZEPAM <input type="checkbox"/> DIAZEPAM <input type="checkbox"/> OXAZEPAM <input type="checkbox"/> TEMAZEPAM <input type="checkbox"/> LORAZEPAM <input type="checkbox"/> FLURAZEPAM | <input checked="" type="checkbox"/> ILLICITS <input type="checkbox"/> MDMA (Ecstasy) <input type="checkbox"/> PHENCYCLIDINE <input type="checkbox"/> K-2 SPICE <input type="checkbox"/> 6 ACETYLMORPHINE (Heroin) <input type="checkbox"/> THC-COH <input type="checkbox"/> METHAMPHETAMINE <input type="checkbox"/> BENZOYLECGONINE |
| <input checked="" type="checkbox"/> BEHAVIORAL <input type="checkbox"/> AMITRIPTYLINE <input type="checkbox"/> DESIPRAMINE | <input checked="" type="checkbox"/> STIMULANTS <input type="checkbox"/> AMPHETAMINE <input type="checkbox"/> NORPSEUDOEPHEDRINE <input type="checkbox"/> METHYLPHENIDATE <input type="checkbox"/> MEPHEDRONE | <input checked="" type="checkbox"/> OTHER <input type="checkbox"/> PHENOBARBITAL <input type="checkbox"/> KETAMINE <input type="checkbox"/> GABAPENTIN <input type="checkbox"/> PREGABALIN |
| <input checked="" type="checkbox"/> COMPREHENSIVE PANEL <input type="checkbox"/> CUSTOM PANEL | | |
| Selection for a parent drug will prompt confirmation of metabolite as well | | |
| Immunoassay Screening | | |
| <input checked="" type="checkbox"/> SPECIMEN VALIDITY (OXIDANTS, SG, pH, CREATININE) <input type="checkbox"/> AMPHETAMINE <input type="checkbox"/> BARBITURATE <input type="checkbox"/> BENZODIAZEPINE <input type="checkbox"/> COCAINE <input type="checkbox"/> OPIATE | <input type="checkbox"/> OXYCODONE <input type="checkbox"/> PHENCYCLIDINE <input type="checkbox"/> PROPOXYPHENE <input type="checkbox"/> PHENOBARBITAL <input type="checkbox"/> METHADONE <input type="checkbox"/> METHAQUALONE <input type="checkbox"/> THC | <input type="checkbox"/> TCA <input type="checkbox"/> ECSTASY <input type="checkbox"/> 6MAM <input type="checkbox"/> BUPRENORPHINE <input type="checkbox"/> COTININE <input type="checkbox"/> FENTANYL <input type="checkbox"/> ETHYL GLUCURONIDE |
| <input checked="" type="checkbox"/> COMPREHENSIVE PANEL | | |

123. CDP then submitted claims to TRICARE for twenty types of toxicology tests purportedly for J.M.'s benefit, including tests for substances such as amphetamines, opiates, methadone, and benzodiazepines. TRICARE paid CDP \$440.60 on the basis of these fraudulent claims.

124. As with Dr. Rao, Bugen and Sheffield paid Dr. Parameswara between \$6,000 and \$8,000 per month for ordering unnecessary toxicology and genetic tests. Dr. Parameswara also provided Bugen with a signature stamp so that ADAR Group employees could order these tests. Again, CDP and Dr. Cockerell caused the claims for payment for these fraudulent tests to be submitted to TRICARE by allowing Progen to submit them using CDP's CLIA license and NPI number. TRICARE paid CDP for the fraudulent claims.

125. Bugen also recruited Dr. Salazar to authorize lab referrals. Bugen had Dr. Salazar provide a signature stamp for the ADAR Group to use on the requisition forms. The ADAR Group paid Dr. Salazar, just as it did Drs. Rao and Parameswara. According to Sheffield, Dr. Rao and Dr. Salazar did no work to justify the payments; Bugen paid the doctors for nothing more than the use of their NPI numbers to generate lab referrals to Progen.

126. Dr. Kim served for a couple months as an independent contractor for the ADAR Group. Dr. Kim terminated the relationship on January 5, 2016 after he discovered that the ADAR Group had been using his signature stamp on lab requisition forms.

127. As detailed below, CDP admitted to TRICARE in 2016 that it submitted thousands of improper claims and received \$4,196,137.42 in wrongful payments. These improper claims were associated with the ADAR Group's fraudulent lab tests.

VIII. SCHEME 1: DEFENDANTS KNOWINGLY SUBMIT, OR AID IN THE SUBMISSION OF, FRAUDULENT LAB TESTS TO TRICARE.

A. Dr. Cockerell became aware of problems with Progen's operations—and that it was submitting claims to federal programs—shortly after signing the MSA.

128. Around June 2015, Dr. Cockerell and CDP learned that Progen was performing services for patients enrolled in federal healthcare programs, including TRICARE. CDP admitted this in a demand for arbitration against Progen in February 2017, as shown in the excerpt below:

21. Around June 2015, Cockerell learned that, in breach of the express terms of the MSA, ProGen had been performing services for patients enrolled in Medicare, Medicaid, and other federal or state healthcare programs, including TriCare. Indeed, despite their assurances to the contrary, it appears that the Principals had always planned to perform services for patients enrolled in these programs.

129. Further, according to CDP in its demand for arbitration, Progen's mismanagement "began on day one." In the arbitration demand, CDP faulted Progen for failing to operate the lab consistent with existing regulations; failing to oversee sales personnel; employing family members; and utilizing fraudulent accounting, self-dealing, improper sales practices, and gross financial mismanagement. Despite this, CDP continued to permit Progen to use its CLIA license and NPI number to submit claims for payment to TRICARE and Medicare.

130. On June 9, 2015, Quintan emailed Progen's current billing data to Dr. Cockerell. It showed that TRICARE was Progen's highest payor, as shown in the excerpt below (highlight added):

| Payer | Total Ins Pay | Count | Average |
|--|---------------|-------|------------|
| Aetna | \$4,678.48 | 30 | \$155.95 |
| Blue Cross Blue Shield Texas (BCBS TX) | \$118,290.13 | 106 | \$1,115.94 |
| CIGNA | \$9,828.60 | 14 | \$702.04 |
| Humana | \$8,875.09 | 20 | \$443.75 |
| TriCare Palmetto (Regions 1-6) | \$133,124.80 | 96 | \$1,386.72 |
| United Healthcare | \$23,945.74 | 25 | \$957.83 |
| Grand Total | \$298,742.84 | 291 | \$1,026.61 |

131. Notwithstanding that the MSA explicitly prohibited CDP from performing tests for federal beneficiaries—or accepting government receivables—Dr. Cockerell and CDP did not instruct Progen to stop soliciting federal referrals. Instead, Dr. Cockerell and CDP allowed Progen to continue submitting claims to federal healthcare programs, including TRICARE, using CDP's CLIA license and NPI number.

132. TRICARE Palmetto, the TRICARE contractor shown in the excerpt above, paid CDP, not Progen, for the Progen claims. In other words, since CDP let Progen use CDP's CLIA license and NPI number, the reimbursement for the Progen claims flowed directly into CDP's bank account. This setup gave Dr. Cockerell and CDP visibility into the volume of referrals—including federal referrals—that Progen was generating. CDP then passed the money through to Progen. And Progen would owe CDP 20 percent of the net revenue—supposedly limited to non-federal referrals per the MSA. But CDP and Dr. Cockerell wanted a cut of the federal revenue too.

133. CDP collected \$101,347.95 in May 2015 and \$630,979.67 in June 2015 based on claims submitted for Progen's tests. These amounts included both federal and non-federal reimbursements, including approximately \$281,775 from TRICARE.

134. On July 13, 2015, CDP remitted \$101,347 to Progen—i.e. the amount of Progen's May 2015 reimbursements. Dr. Cockerell signed the check for CDP. Before remitting the June 2015 reimbursements, Dr. Cockerell and CDP wanted a better understanding of Progen's financials.

135. On July 15, 2015, Maggie Kipp (CDP's CFO) emailed John Le (Progen's CFO) to express concerns about Progen's financial statements. Kipp noted that the financials, which appeared to use the amount billed by CDP (rather than the amount paid to CDP) as the revenue figure, were "in no way accurate or in keeping with CDP's 20% 'net revenue' agreement with ProGen." Kipp copied Dr. Cockerell, Schuster, Rall, and Quintan on the email.

136. Attached to Kipp's email was Progen's Profit and Loss Statement through May 2015. It showed that Progen had incurred approximately \$1 million in "marketing fees" for its DNA and toxicology testing. It also showed that Progen was writing off all patient copay amounts from the lab tests it was billing through CDP as "Bad Debt." Given that TRICARE prohibits waiving copays, this was another red flag to Dr. Cockerell that CDP should have stopped Progen from using its CLIA license and NPI number to submit claims to TRICARE. He did not. Instead, Dr. Cockerell focused on calculating and extracting his cut of the revenue from Progen.

137. The next day, July 16, Dr. Cockerell participated in a call about Progen's financials, billings, and collections. In a follow-up email, Dr. Cockerell noted that “[o]ur arrangement with Progen is to receive 20% of the overall net collected revenue.” Dr. Cockerell emphasized that CDP needed to better understand Progen's expenses, and specifically noted “an almost 1M line item for SGA” (Selling, General & Administrative), as shown in the excerpt below:

One other item we need to understand is the budget which includes expenses. We noted an almost 1M line item for SGA. We would like to see detailed documentation of all of these expenses as these obviously affect our profit from the venture.

I will work this weekend on a list of items for discussion at our meeting on Tuesday which I will circulate to you and others to review and add to.

138. As shown above, Dr. Cockerell asked for “detailed documentation” on Progen's SGA expenses. Progen's SGA expenses were its commission payments to its various marketers including, in particular, the Hawrylaks and the ADAR Group. And Dr. Cockerell planned to address these issues with Progen's principals at an upcoming meeting.

139. On July 20, 2015, Hal Rose (CDP's legal counsel and business development officer) circulated an agenda for the “Progen Lab and CDP Strategic Meeting” to Dr. Cockerell, Schuster, Rall, Quintan, Le, Kipp, Brenda Cockerell, and Bryon Hammer (Progen's outside counsel). The agenda included a discussion of the MSA; the relationship between CDP and Progen; lab operations; and billing and collection and related financial items. The agenda specifically included a discussion of (1) Progen's federal healthcare program referrals and (2) Progen's sales network, as shown in the excerpt below:

4. Miscellaneous items:

- a. We need to understand the type of business that is being billed with respect to for example Medicare/Medicaid items that are not generally contemplated under the agreement
- b. Discussion of their sales network and how it operates; MSO arrangements they have in place; how we can work to drive greater sales

140. Dr. Cockerell and CDP not only knew that Progen used a network of marketers to generate referrals, but, as shown in the excerpt above, they also wanted to know the details of how it worked. In fact, Dr. Cockerell and CDP were focused on how they could work with the marketers “to drive greater sales,” that is, more referrals to Progen and CDP.

141. Attendees at the July 21 “strategic meeting” included Dr. Cockerell; his wife, Brenda; Kipp; Rose; and the four Progen principals.

142. By this point, Dr. Cockerell and CDP knew: (1) the MSA implicated the AKS and did not any exception or safe harbor to the AKS; (2) despite the carve-out in the MSA, Progen was submitting claims to federal healthcare programs, including TRICARE, using CDP’s CLIA license and NPI number; and (3) Progen was paying significant commissions to marketers and waiving patient co-pays.

143. But Dr. Cockerell and CDP did not put a stop to the arrangement—or the submission of claims to TRICARE. Instead they focused on how to continue paying commissions to Progen’s marketers to “drive greater sales” of toxicology and PG testing.

144. To that end, one item discussed at the July 21 strategic meeting was moving Progen’s marketers onto CDP’s payroll as “co-employees,” ostensibly in a weak attempt to meet the bona fide employee exception or safe harbor of the AKS. That never happened. Moreover, it prompted CDP’s CFO to raise concerns directly to Dr. Cockerell

about CDP’s relationship with Progen and the possibility that CDP and Dr. Cockerell were on the hook for submitting false claims to federal healthcare programs. Despite all of this, Dr. Cockerell kept submitting Progen’s claims to TRICARE using CDP’s CLIA license and NPI number.

B. CDP’s CFO developed significant concerns about FCA violations and raised those concerns to Dr. Cockerell.

145. On July 29, 2015, Le reached out to Kipp about transitioning Progen’s sales reps (which would include, for example, the Hawrylaks) to CDP’s payroll. Le stated that the “first commission run” would be on August 14.

146. Kipp forwarded Le’s email to Dr. Cockerell, Brenda Cockerell, and Hal Rose. Dr. Cockerell responded that he also wanted to contact the sales reps about “dermpath marketing.” In other words, Dr. Cockerell also wanted to leverage Progen’s marketers to increase “sales” of CDP’s legacy dermatopathology lab services.

147. Kipp replied to Dr. Cockerell that “adding 400 co-employees to our existing 65 person payroll will almost immediately trigger [a] Texas Workforce Commission audit and CDP will be under additional scrutiny when an additional 300-400 employees are added later this year (total of 700-800 co-employees by year end.).”

148. Dr. Cockerell responded to Kipp that “[w]e will not assume a significant amount of risk or work without compensation.” Kipp answered: “We really need to talk in person and fully discuss all these issues.” In a follow-up email, also dated July 29, 2015, Kipp referenced the “numerous risks that have not been brought to your attention -- even by Hal.” Kipp asked to meet with Dr. Cockerell and Brenda Cockerell.

149. As shown in the excerpt below, Dr. Cockerell replied to Kipp that he and CDP would do “whatever it takes” to mitigate the risks and transfer them to Progen. Dr. Cockerell added that “they will have to deal with it so that CDP is not saddled with risk.” Dr. Cockerell finished by noting that “all risk can be lessened,” and “[e]ven skydiving can be done safely!”

From: Clay J. Cockerell, MD
Sent: Wednesday, July 29, 2015 6:22 PM CDT
To: Maggie Kipp
CC: BRENDA COCKERELL
Subject: RE: Can we meet next week to discuss CDP sales reps transition?

Yes and we will do whatever it takes to mitigate them and transfer them to ProGen.

All information you present will be discussed with them and they will have to deal with it so that CDP is not saddled with risk.

They are extremely motivated as you know to get this done so that the business can proceed. They have big \$ invested in this venture and at the end of the day, they will do whatever we say to lessen it and keep it manageable. If we need another high power attorney to weigh in on this other than Hal, we will get someone at their expense to do that.

All risk can be lessened and we will do whatever it takes to make sure that this happens. Even skydiving can be done safely!

150. Around this same time, Dr. Cockerell instructed Kipp to stop putting things in writing.

151. But Kipp continued to press her concerns to Dr. Cockerell. On July 30, she met with Dr. Cockerell and Brenda Cockerell and expressed alarm that CDP was receiving federal payments generated by Progen. When Dr. Cockerell told Kipp that they were not at risk, Kipp told Dr. Cockerell to read the False Claims Act.

152. Dr. Cockerell did nothing in the face of Kipp’s warnings about the potential submission of false claims to federal healthcare programs by CDP and Progen. On July 31, Kipp emailed Le, copying Dr. Cockerell, Quintan, Schuster, and Rall, that “the full

\$630,979.67 collected for June has been paid” from CDP to Progen. This amount included both federal and non-federal reimbursements, including approximately \$278,903 from TRICARE. Despite this ever-increasing violation of the MSA’s prohibition on federal government referrals and receivables, Dr. Cockerell and CDP continued to allow Progen to bill federal healthcare programs, including TRICARE, using CDP’s CLIA license and NPI number.

153. From May through July 2015, CDP submitted approximately 817 false claims to TRICARE for Progen tests, and TRICARE paid CDP approximately \$1,042,073 for those false claims. In the month of July alone, CDP submitted approximately 581 false claims to TRICARE for Progen tests and received approximately \$760,297 in reimbursement.

154. CDP and Progen abandoned the so-called “co-employee” plan. On October 8, 2015, Le emailed Kipp that Progen and CDP had moved away from having shared employees. Kipp forwarded the email to Dr. Cockerell, Brenda Cockerell, and Hal Rose: “If this is correct, then we can stop the payroll set-up but want to discuss with you first before halting all our set-up.”

155. The next day, October 9, Kipp emailed CDP’s outside accountants instructing them to stop working on the “co-employee project” and to send a final bill for the work.

C. Progen began paying CDP a “Practice Operator Expense” for its use of CDP’s CLIA license and contracts.

156. As an enrolled TRICARE and Medicare provider and owner of a CLIA-certified lab, Dr. Cockerell knew that CDP had to submit true and accurate claims to federal healthcare programs. But Dr. Cockerell knowingly disregarded this obligation because Progen’s federal program business was lucrative—and because Progen started paying CDP a cut of the proceeds.

1. CDP and Dr. Cockerell disregarded further red flags about Progen and instead insisted that Progen make payments to CDP.

157. Dr. Cockerell monitored Progen’s financial situation in the weeks after the July 29 meeting. On August 4, 2015, Kipp emailed Le, copying Dr. Cockerell, asking when Progen’s financials would be available for discussion. Kipp wrote: “For these initial financials, it may be best to meet and discuss – it is likely Brenda and Dr. Cockerell would both like to participate in review, as well.”

158. Le sent Progen’s financials to Kipp on or around August 12. Kipp scheduled a meeting with Le for August 27. On the day of the meeting, Kipp emailed Le a list of questions about Progen’s financials, including whether the nearly \$2 million in marketing fees for “DNA” and “Tox” were all commissions.

159. Kipp also forwarded her email to Dr. Cockerell, Brenda Cockerell, and Rose. It attached Progen’s financial statements, which indicated that Progen had continued to write off the full amount of “Patient Copay Income” through June 2015 (\$246,156.42) as “Bad Debt.” Kipp informed the Cockerells: “I will also ask again about distribution of your funds through 6/30/15.”

160. For the month of August 2015, CDP submitted approximately 484 false claims to TRICARE for Progen's tests. TRICARE paid CDP approximately \$608,418 for these false claims. For May through August 2015, TRICARE paid CDP approximately \$1,650,491 for Progen's tests. In just four months, Progen's TRICARE revenue had exceeded CDP's entire 2014 TRICARE revenue by over 650 percent.

161. On September 9, John Barker at PracticePointe (Progen's billing company) sent Kipp and Le Progen's final August collections—\$1,082,547. Kipp forwarded the email to Dr. Cockerell, Brenda Cockerell, and Rose. Dr. Cockerell responded: "Are they beginning to show any profit yet?"

162. On September 10, Kipp again emailed Dr. Cockerell, Brenda Cockerell, and Rose about Progen's expenses and the expected payment to CDP, as shown in the excerpt below:

John Le and I had a good meeting today and are going to meet again Monday afternoon to discuss other items. I have answers and greater understanding on ProGen's expected profitability, expenses to date and allocations.

The way they account for "Practice Operator Expense" (CDP-Cockerell money) is very clear and fair.

There is a lot to cover so we will want to meet and summarize in person.

163. On September 17, 2015, Kipp emailed Brenda Cockerell and Dr. Cockerell about "Cash Big Picture." Kipp wrote:

I'll explain more on Monday and detail our cash projections for you and Dr. Cockerell. We are draining cash from all sides right now BUT – with Legacy paid off today we are \$2 million richer per year! When ProGen starts paying for rented space on 4/1/2016 and we, hopefully, finish building by 12/31/15 we will have an additional \$1.2 million cash per year. This is \$3 million cash swing due purely to Quest payment and DDG. With the projected \$5 million in distributions to you and Dr. Cockerell in 2016 from ProGen – you will be able to finance many (possibly all) of the projects on your horizon.

164. As CDP was "draining cash from all sides," it continued to submit Progen's claims to TRICARE. For the month of September 2015, CDP submitted approximately

923 false claims to TRICARE for Progen tests. TRICARE paid CDP approximately \$603,352 for these false claims.

165. Meanwhile, patients began to complain to CDP about the Progen tests. Although Progen did not attempt to collect the patient copays, patients still received “Explanation of Benefits” forms with CDP’s name showing how much the patients owed. On October 15, Quintan sent the following email about a “major problem,” as shown in the excerpt below:

From: Quintan Cockerell
Sent: Thursday, October 15, 2015 11:27 AM CDT
To: Mark Faselle
CC: Clay J. Cockerell, MD; Dustin Rail; Scott Schuster; Luke Zeutzius
Subject: Patient Complaints

Mark

Dr C mentioned to me today that a few complaints had come thru re very high out of pockets. Do you happen to know what tests were done and what provider it was? Would like to investigate this. Obviously this is a major problem and we need to make sure it doesn't continue

166. On October 20, Kipp forwarded Progen financials through September 30, 2015 to Dr. Cockerell, Brenda Cockerell, and Rose: “Net income through 9.30.15 is almost \$1,575,503, at 20% net ownership interest this is \$315K.” The attached spreadsheet showed that Progen was still writing off the full amount of “Patient Copay Income” (\$569,277.98) as a “Bad Debt” expense.

167. Progen’s spreadsheet also showed that the toxicology and PG “marketing fees” were broken down into “1099” and “W2” categories. But CDP had stopped the “co-employee” project. CDP never added Progen’s marketers to its payroll—though it continued to accept payment from TRICARE and other federal healthcare programs for Progen’s referrals.

168. On October 30, 2015, Progen issued a \$200,000 check to CDP. Progen and CDP called this payment a “Practice Operator Expense.”

169. For the month of October 2015, CDP submitted approximately 1,990 false claims to TRICARE for Progen tests. TRICARE paid CDP approximately \$331,324 for these false claims.

170. On November 9, 2015, Kipp emailed Le, copying Dr. Cockerell, Brenda Cockerell, and Rose, about the status of the CDP-Progen financial reconciliation. Kipp asked: “Will Brenda and Dr. Cockerell receive another \$200,000 payment in November? Is there also an additional \$200,000 to be paid in December?” Le confirmed that Progen would try to make both payments.

171. On November 30, 2015, Kipp emailed Le to ask if the \$200,000 payment to Brenda and Dr. Cockerell would be available. Kipp again copied Dr. Cockerell.

172. For the month of November 2015, CDP submitted approximately 3,711 false claims to TRICARE for Progen tests. TRICARE paid CDP approximately \$1,074,233 for these false claims. In other words, in just one month, Progen’s tests more than quadrupled CDP’s entire TRICARE reimbursement from 2014.

173. On December 3, 2015, Progen issued a \$258,228 check to CDP. That payment included \$200,000 to CDP for the Practice Operator Expense.

D. After receiving multiple patient complaints, CDP adopted an assumed name to hide its role in the scheme.

174. Patient complaints about Progen's testing accelerated in December. On December 18, Faselle (CDP VP of Health Plans) emailed Progen, copying Rose, about an "urgent issue," as shown in the excerpt below:

We have an urgent issue that needs to be handled immediately, over the last few days our customer service team has received angry phone calls from Progen patients who are incensed with the large balance on their bill. Each person has either threatened to turn us in to the Medical Advisory board or contact Medicare and report a fraud case. Our customer service team has tried to contact Practice Pointe 7-8 times yesterday to help resolve these issues and Practice Pointe did not return any of our calls. I am not sure if Practice Pointe is still the billing unit responsible for these Progen claims, if not then this is something our team needs to be made aware.

175. Rose responded that he, Faselle, and Le were on it.

176. Around this same time, CDP's CFO Kipp was in the lab talking to a CDP customer service employee. The employee told Kipp that CDP had received a telephone call from an individual asking, "When will we receive our gift cards? We have not received our gift cards." This caused Kipp further concern.

177. On December 28, Dr. Cockerell forwarded Le, Quintan, Rose, and Faselle a patient complaint addressed to CDP. The patient even expressed concern that someone may have stolen his identity to defraud his health insurance, as shown in the excerpt below:

I am writing you because I believe my identify has been stolen and that the perpetrator used my identify to purchase services from your organization. I am attaching a bill I received yesterday for what appears to be genetic testing services. I never ordered and never received these services. I will be notifying the credit reporting agencies that someone has stolen my identity and that services were neither requested by nor rendered to me by Cockerell Dermatopathology PA. I really would like to speak with someone from your office to discuss this issue further and will be calling your office on Monday.

Please note that there are some insurance payments on this bill. I tried to call my health insurance company, Aetna, today, however the office is closed. I will retry on Monday. I would like to know whether my health insurance also was used as part of this fraud.

178. In his email attaching the complaint, Dr. Cockerell stated bluntly: “He’s calling the entire business fraud.”

179. Also on December 28, Dr. Cockerell notified Le, Quintan, Rose, Faselle, and Wander that a different patient had filed a complaint against him with the Texas Medical Board about excessive fees. Dr. Cockerell wrote:

Do you have a list of all the patients that have had any issues with any charges and how they were handled? Going forward, we need to have this on a proactive basis so we can interact with you guys in dealing with them. We’ve been dealing with these issues for many years and it’s often a little old lady or man who gets an EOB and reads it and thinks the charges are “outrageous” and then files a complaint that we have to deal with. The board keeps all the complaints on file and looks for patterns so we will need to prepare a response that describes our entire business to them and how this happened in all likelihood and how we plan to ensure that is has been rectified and won’t happen in the future.

180. Dr. Cockerell concluded the email: “*At the end of the day, ultimately I am responsible and this puts me at risk like this*” (emphasis added).

181. Despite this, CDP and Dr. Cockerell did not stop permitting Progen to submit medically unnecessary false claims to federal healthcare programs, including TRICARE. In fact, CDP submitted approximately 1,246 claims in December 2015 and 375 claims in January 2016 for Progen tests. TRICARE paid CDP approximately \$633,746 and \$159,276 for these two months, respectively.

182. Following these patient complaints, Dr. Cockerell and Progen made a coordinated effort to disguise CDP's involvement in the PG and toxicology tests going forward. On or around December 31, 2015, both CDP and Progen filed documents with the Texas Secretary of State for the same assumed business name: Origen Laboratories. Dr. Cockerell sent an email to Progen's principals on December 31 confirming that CDP submitted its "dba" filing.

183. On January 7, 2016, Le emailed Progen's outside counsel, copying Faselle, Rose, and Progen's principals, and stated that Progen wanted to change the appearance of its bills because patients were calling CDP's customer service line with complaints. Rose responded to the group: "Dr. Cockerell is also reviewing. I know that he wants to eliminate as many direct references to CDP as possible."

184. In other words, by using the same assumed name, CDP and Progen tried to make it harder for patients to identify CDP's role in the scheme. Even though CDP would still be the entity submitting claims to the patients' insurance, patients would direct their future complaints against Origen, which was also now a name for Progen.

185. During this process, Progen continued to pay CDP the Practice Operator Expense. On January 4, 2016, Progen issued another \$200,000 check to CDP, bringing the total payment to \$600,000.

186. From July 30, 2015—when Kipp warned Dr. Cockerell specifically about FCA violations—through the end of the MSA in November 2016, Dr. Cockerell and CDP caused approximately 10,615 false claims to be submitted to TRICARE. They caused the submission of these false claims by allowing Progen to use CDP's CLIA license and NPI

number despite: (1) the MSA’s prohibition on accepting federal payments; (2) multiple red flags that Progen was paying illegal commissions to its marketers and waiving patient copays; (3) their knowledge that Progen had engaged in gross mismanagement from “day one;” and (4) patient complaints accusing CDP of fraud. TRICARE paid CDP approximately \$4,099,787 for these false claims.

E. CDP admitted almost \$1 million in false TRICARE claims.

187. Around January 8, 2016, Quintan and Le told Kipp that Progen had lost money in 2015, and they asked CDP to return the \$600,000 in Practice Operator payments to Progen. But CDP and Dr. Cockerell kept the money.

188. On or around January 10, 2016, CDP received another patient complaint about how a cheek swab—one of Progen’s PG tests—turned into a \$6,799 charge from CDP. The patient complained about the “fraudulent and predatory scheme,” as shown in the excerpt below:

January 10, 2016

Cockerell Dermatopathology PA
2110 Research Row, Suite 100
Dallas, TX 75235

I dispute the charges by Cockerell Dermatopathology PA billed to me in the amount of \$6,799 on December 24, 2015 as being medically unnecessary and part of a fraudulent and predatory scheme and demand that you remove those charges and provide written confirmation of their reversal by January 22, 2016 or I will be forced to take further legal action.

189. On January 11, 2016, Dr. Cockerell, Quintan, Faselle, and Le met with Rohan Nath (Progen’s new biller) at CDP. The next day, one of Nath’s employees

submitted to TRICARE a retraction letter and list of claims. The letter was written on CDP letterhead and used CDP's Tax ID and NPI number, as shown in the excerpt below:⁵

COCKERELL DERMATOPATHOLOGY, LLC
2110 RESEARCH ROW, SUITE 100
DALLAS, TX 75235-2519

Date:- 01/12/2016

Tricare South Region
PO Box 7032
Camden, SC- 29021

Practice Name:- Cockerell Dermatopathology, LLC
TAX ID:- [REDACTED]
NPI:- 1528300837

Re: Retractions of claims submitted in error due to internal system issue.

190. The retraction letter acknowledged that CDP had submitted certain claims to TRICARE "in error." It further represented that CDP "will refund any paid amounts upon receipt of refund letter from Tricare," as shown in the excerpt below:

I am writing this letter to inform Tricare of an error that we have identified internally at our end and impacts quite a few number of claims. While doing an internal audit, it has come to our attention that there are few claims that were submitted in error to Tricare due to some system issue at our end. Some of these claims have been processed and paid as well.

We would like Tricare to retract/void the attached list of claims in their system as these were submitted in error and issue us a letter asking for refund or informing us of claims being voided out in their systems. We will refund any paid amounts upon receipt of refund letter from Tricare.

191. The purported explanation for these false claims—"some system issue"—was not true. Progen and CDP had deliberately submitted these claims to TRICARE. CDP neglected to inform TRICARE that these claims were generated by a fraudulent

⁵ CDP's Tax ID is redacted throughout this Complaint.

marketing scheme where marketers gave patients Wal-Mart gift cards in exchange for urine samples.

192. The retraction letter attached two sets of erroneous claims. The first attachment included a list of 45,920 claims from July 7 through October 30, 2015. According to the attachment, CDP had received \$641,196.05 from TRICARE for these erroneous claims. The second attachment included another 528 claims ranging from November 3 through November 20, 2015. And it indicated that TRICARE had paid CDP an additional \$300,654.72 for these erroneous claims.

193. These claims were just a subset of the fraudulent claims associated with the ADAR Group. According to an email between Progen employees Eric Hahn and Mary Olson, the claims related to three doctors affiliated with the ADAR Group's Jody Sheffield: Yun Kim, Vinay Parameswara, and Sakshi Malhotra. But CDP did not disclose to TRICARE any claims associated with Sekhar Rao or Alex Salazar, who were also ADAR Group physicians that had been generating significant Progen lab referrals to CDP.

194. Excerpted below is a sample of ten claims (with patient information redacted) from one of the attachments to CDP's retraction letter. CDP acknowledged to TRICARE that these ten claims—along with the thousands of others in the two attachments—were erroneous and required repayment by CDP to TRICARE:

| | | |
|-------------------------------|--|--|
| Cockerell Dermatopathology PA | | |
| NPI#: 1528300837 | | |
| Tax ID#: | | |

| Sr.No | Patient Name | Date of Birth | Referring Provider | Policy Number | ICN Number | Date of Service | Billed Amount | Paid Amount |
|-------|--------------|---------------|--------------------|---------------|------------|-----------------|---------------|-------------|
| 1 | | | Kim, Yun | | | 11/3/2015 | \$ 2,254.00 | \$ 798.24 |
| 2 | | | Kim, Yun | | | 11/3/2015 | \$ 2,254.00 | \$ 643.11 |
| 3 | | | Kim, Yun | | | 11/3/2015 | \$ 2,254.00 | \$ 643.11 |
| 4 | | | Kim, Yun | | | 11/3/2015 | \$ 2,254.00 | \$ 643.11 |
| 5 | | | Kim, Yun | | | 11/3/2015 | \$ 1,540.00 | \$ 534.44 |
| 6 | | | Kim, Yun | | | 11/3/2015 | \$ 714.00 | \$ 263.80 |
| 7 | | | Kim, Yun | | | 11/3/2015 | \$ 2,254.00 | \$ 546.64 |
| 8 | | | Kim, Yun | | | 11/3/2015 | \$ 2,254.00 | \$ 798.24 |
| 9 | | | Kim, Yun | | | 11/3/2015 | \$ 2,254.00 | \$ 643.11 |
| 10 | | | Kim, Yun | | | 11/10/2015 | \$ 2,254.00 | \$ 798.24 |

195. As another illustration, the excerpt below shows several of the claims associated with Dr. Vinay Parameswara that CDP admitted needed to be repaid to TRICARE (patient information redacted):

| | | | | |
|-----|--------------------|-----------|-------------|-----------|
| 267 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 643.11 |
| 268 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 798.24 |
| 269 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 631.11 |
| 270 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 643.11 |
| 271 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 546.64 |
| 272 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 643.11 |
| 273 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 643.11 |
| 274 | Parameswara, Vinay | 11/6/2015 | \$ 2,254.00 | \$ 798.24 |

196. TRICARE requested a refund of \$923,606.44 from CDP in response to CDP's retraction letter.

197. But this first retraction letter did not cover all of the ADAR Group claims. And CDP did not stop submitting the Progen claims to TRICARE. Despite Dr. Cockerell's and CDP's efforts to hide their role in the scheme through the fictitious "Origen Labs" name, they soon got media attention.

F. After a CBS Evening News report accused CDP of fraud, CDP disclosed to TRICARE another \$3.27 million in false claims.

198. On February 5, 2016, the Dallas Morning News reported that Rxpress was accused of paying illegal kickbacks to physicians and commissions to sales reps. The article also reported that Schuster and Rall had received commissions on TRICARE referrals, and it identified Xpress Labs—another name used by Progen—for possible

TRICARE fraud associated with lab tests. That same day, Rose forwarded the article to Dr. Cockerell, Kipp, and Faselle. Kipp sent Quintan, copying Dr. Cockerell, contact information for a crisis PR specialist.

199. Even after the Dallas Morning News article came out, Dr. Cockerell did not stop Progen from submitting claims to TRICARE using CDP's NPI and CLIA license. For the month of February 2016, CDP submitted approximately 207 claims to TRICARE for Progen tests. TRICARE paid CDP approximately \$84,906 for these claims.

200. In late March 2016, CBS contacted Dr. Cockerell with questions about CDP's toxicology and genetic testing. CDP retained a PR team to help with the response. On April 4, one member of the PR team, John Jannarone, emailed that CBS had discovered that both CDP and Progen were using the Origen business name. He noted that “[t]hey look at this as if Progen is using Dr. Cockerell's CLIA license and insurance contracts in some sort of underhanded way,” as shown in the excerpt below:

I spoke to Len and Emily at CBS and they apparently found the DBA documents themselves since we spoke on Friday. They are aware that Origen is a DBA for both CDP and Progen.

At this point, we need to give them more details to avoid confusion. They look at this as if Progen is using Dr. Cockerell's CLIA license and insurance contracts in some sort of underhanded way.

201. CDP and Progen continued to engage with CBS through the PR team. On May 31, 2016, CBS reporter Emily Rand emailed a list of questions related to suspicious toxicology and PG testing, several of which are excerpted below:

1. Did Cockerell Dermopathology, a.k.a. Origen labs a.k.a. Xpress Laboratories begin running toxicology and pharmacogenetic (PGX) specimens in March 2015?
2. Did Cockerell Dermopathology a.k.a. Origen a.k.a. Xpress Laboratories labs begin running hereditary cancer testing specimens in October 2015?
3. Is it accurate to report that for a period time starting around June 2015 until at least December 2015, Cockerell Dermopathology accepted toxicology/PGX/Hereditary cancer specimens from patients with Tricare insurance who went to clinics in Killeen, TX located at 1003 10th St., 805 8th St and 307 W Veterans Memorial Blvd? The clinics were known variously as "Beyond Recovery" "Adar Group" and "Killeen Health and Wellness".
4. Is your lab aware these patients were incentivized to sign up for the tests with \$50 Wal-Mart gift cards?

202. Rand also asked: "Were you aware the doctors ordering these tests were Dr. Sekhar Rao of Austin, Dr. Vinay Kumar Parameswara of Austin, Dr. Yun Kim of Austin and Dr. Alex Salazar of El Paso, TX, and that these doctors did not physically see patients for whom they ordered tests?" The PR specialist forwarded Rand's questions to Dr. Cockerell, Quintan, Rose, and several others on the crisis management team.

203. At the time of Rand's email, the ADAR Group had generated over \$4 million in fraudulent TRICARE reimbursements to CDP. But CDP had only disclosed \$923,606 of that amount to TRICARE. And it had not paid any of the money back.

204. Moreover, CDP and Dr. Cockerell continued to submit claims to TRICARE for Progen tests as the CBS inquiry unfolded. From March through May 2016, CDP submitted approximately 843 Progen claims to TRICARE, and TRICARE paid CDP approximately \$191,957 for those claims.

205. On June 8, 2016, CBS Evening News aired a story titled “U.S. military members duped to help pull off insurance fraud.”⁶ CBS reported that CDP submitted fraudulent lab tests to TRICARE, and it featured a soldier’s wife—a TRICARE beneficiary—who claimed she received Wal-Mart gift cards for providing urine samples. Although CBS did not identify the ADAR Group by name, their fraudulent scheme was the basis for the story.

206. The CBS story also included an interview of Dr. Cockerell, who denied CDP’s involvement saying: “That’s not my lab.” The CBS reporter then added: “In a written statement, representatives of Cockerell Dermatopathology confirmed it is his lab.”



Dr. Clay Cockerell. / CBS NEWS

207. As reported by CBS, CDP “said it is voluntarily refunding what it calls ‘significant amounts of money’ – but wouldn’t say how much or to whom.”

208. One week after the CBS story, CMS conducted an on-site inspection at CDP.

⁶ <https://www.cbsnews.com/news/us-military-members-duped-to-help-pull-off-insurance-fraud/> (last visited on March 17, 2021).

209. Two weeks after the CBS story, on June 22, Eric Hahn—on behalf of CDP—submitted a second “Retraction of claims” letter to TRICARE. It attached another list of erroneous claims, which CDP admitted “were improperly submitted to Tricare.” The letter further represented that CDP would “refund any paid amounts upon receipt of refund letter from Tricare.” Like the first retraction letter, it was on CDP letterhead with CDP’s NPI and Tax ID number, as shown in the excerpt below:

COCKERELL DERMATOPATHOLOGY, LLC
2110 RESEARCH ROW, SUITE 100
DALLAS, TX 75235-2519

Date: 06/22/2016

Tricare South Region
PO Box 7032
Camden, SC 29021

Practice Name: Cockerell Dermatopathology, LLC
TAX ID: [REDACTED]
NPI: 1528300837

Re: Retraction of claims submitted

210. The letter attached a spreadsheet that included approximately 4,802 claims submitted to TRICARE between June 29 and December 23, 2015. These claims were on the basis of additional fraudulent lab tests associated with the ADAR Group—specifically, lab referrals from Dr. Sekhar Rao and Dr. Alex Salazar. TRICARE paid CDP \$3,272,530.98 on the basis of these fraudulent claims—claims that CDP admitted should not have been submitted to TRICARE.

211. A sample of ten claims (with patient information redacted) excerpted from the attachment to CDP’s second retraction letter is shown below. CDP acknowledged to

TRICARE that these claims—as with the thousands of others in the attachment—were erroneous and required repayment by CDP to TRICARE:

| | | | | | | | |
|--------------------------------------|--|--|--|--|--|--|--|
| Cockerell Dermatopathology PA | | | | | | | |
| NPI#: 1528300837 | | | | | | | |
| Tax ID#: [REDACTED] | | | | | | | |

| Acct ID | Patient Name | Birth Date | Ref Provider | Claim ID | Service Date | Billed | Pmt |
|----------|--------------|------------|---------------|-----------------|--------------|------------|----------|
| CDP.112 | | | RAO, SEKHAR | B317X56DB-00 | 11/02/2015 | \$1,835.00 | \$18.37 |
| CDP.112 | | | RAO, SEKHAR | B336X5FX8-00 | 11/02/2015 | \$2,204.00 | \$624.74 |
| CDP.920 | | | SALAZAR, ALEX | B350X580V-00 | 11/06/2015 | \$2,254.00 | \$798.24 |
| CDP.912 | | | SALAZAR, ALEX | B322X5PL8-00-00 | 11/06/2015 | \$2,254.00 | \$643.11 |
| CDP.1013 | | | RAO, SEKHAR | B322X5PN7-00-00 | 11/06/2015 | \$2,254.00 | \$798.24 |
| CDP.1776 | | | SALAZAR, ALEX | B322X5PQ7-00-00 | 11/03/2015 | \$2,254.00 | \$643.11 |
| CDP.927 | | | SALAZAR, ALEX | B322X5PLW-00 | 11/03/2015 | \$2,254.00 | \$643.11 |
| CDP.921 | | | RAO, SEKHAR | B322X5PJY-00-00 | 11/06/2015 | \$2,254.00 | \$798.24 |
| CDP.946 | | | RAO, SEKHAR | B350X580H-00 | 11/06/2015 | \$2,254.00 | \$798.24 |
| CDP.1073 | | | RAO, SEKHAR | B322X5PNM-00-00 | 11/03/2015 | \$2,254.00 | \$643.11 |

212. Together, CDP’s retraction letters to TRICARE in January 2016 and June 2016 reported \$4,196,137.42 in improper claims that CDP admitted needed to be refunded.

213. TRICARE did not send a refund letter to CDP in response to the second retraction letter. On August 23, 2016, Hahn noted the claims were still under review by TRICARE. On November 22, 2016, the United States Attorney’s Office confirmed to CDP through its counsel that an FCA investigation into CDP was already open.

214. Progen’s business declined after the CBS story aired, but CDP continued to submit claims to TRICARE for Progen’s tests. From June 2016 through November 2016, CDP submitted another approximately 817 Progen claims to TRICARE, and TRICARE paid CDP approximately \$69,370 for those claims.

IX. SCHEME 2: DEFENDANTS KEEP PAYMENT FROM TRICARE FOR FALSE CLAIMS AND IGNORE OBLIGATION TO REPAY FUNDS.

A. CDP terminated the MSA with Progen.

215. On July 28, 2016, D Magazine published an article titled “Baylor Taps the Brakes on Replacing the Chairman of its Dermatology Program.”⁷ According to the article, Dr. Cockerell wrote in an email: “The lab that is managed by ProGen performed tests on specimens that were sent to us that were induced by dishonest individuals. We learned about it over nine months ago.” By that account, Dr. Cockerell and CDP learned about the fraudulent inducement of lab tests as early as October 2015.

216. On November 15, 2016, CMS informed Dr. Cockerell that Origen Laboratories (i.e. Progen’s lab) required its own CLIA number, as shown in the excerpt below:

A CLIA application (signature date of 02/26/15) was submitted to add the subspecialty of toxicology. Based on review of the documents, it was approved on May 13, 2015. However, the documentation did not indicate that the owners of Origen/ProGen and Cockerell Dermatopathology PA were the same. Based on the complaint survey, it was identified that the two entities were actually separate and have separate owners. Therefore, the approval to add toxicology to the CLIA number 45D2057348 would not have been authorized if the correct ownership information had been provided to CMS.

Therefore, CMS is requiring Origen/ProGen obtain a new CLIA number. CMS will not allow Origen/ProGen to share the CLIA number with Cockerell Dermatopathology. Since both entities are for profit and have separate ownership, they do not meet any of the CLIA exemptions as listed under 42 CFR 493.4342 C.F.R. § 493.807.

217. Although CDP’s PG and toxicology referrals from Progen had slowed by this point, CDP stopped submitting claims based on its agreement with Progen following the letters from the United States Attorney’s Office and CMS-CLIA.

⁷ <https://www.dmagazine.com/healthcare-business/2016/07/baylor-taps-the-brakes-on-replacing-chairman-of-dermatology-program/> (last visited on March 17, 2021).

218. CDP terminated the MSA in November 2016. On November 18, CDP and Progen executed an “Assignment and Assumption Agreement.” Progen transferred its accounts receivable to CDP in exchange for: (1) up to \$95,000 for employee-related expenses and other expenses; (2) the ongoing D&O policy premiums for Progen; and (3) Progen’s attorneys’ fees.

219. Starting on December 1, 2016, CDP started making payments to TRICARE. CDP reimbursed only \$588,799.65 of the nearly \$4.2 million in fraudulent claims that it disclosed to TRICARE. And while CDP sued Progen in an attempt to make up the difference, Dr. Cockerell decided to keep the money for himself.

B. CDP successfully sued Progen for \$3.485 million, but it kept the proceeds rather than repay TRICARE.

220. On February 6, 2017, CDP filed a demand for arbitration and statement of claim against Progen and its four principals. CDP alleged that Progen and its principals committed fraud, breach of contract, and negligence by inducing Dr. Cockerell to enter a business relationship whereby Progen would act as a third-party operator of Dr. Cockerell’s laboratory. CDP alleged that Progen and its principals did not have the knowledge, experience, or resources necessary to fulfill their obligations under the MSA.

221. Dr. Cockerell knew from the very outset that Progen’s principals were not qualified to run a clinical lab. They were not doctors. They were not healthcare providers. They did not have a CLIA license. And yet Dr. Cockerell and CDP submitted Progen’s claims to TRICARE anyway—because they were given a cut of the proceeds.

222. In its arbitration demand, CDP stated that it learned in June 2015 that Progen had breached the MSA by performing services for federal beneficiaries. And CDP further alleged that Progen’s “sales representatives engaged in illegal and unethical behavior almost immediately after executing” the MSA, which resulted in harm to CDP when the CBS report came out.

223. On February 28, CDP filed an amended demand for arbitration. CDP invoked its indemnification provision under the MSA, and CDP asserted that it anticipated paying “millions of dollars” to the government. CDP sought reimbursement from Progen for its “forthcoming settlement,” as quoted below:

58. As a result of ProGen’s fraud and negligence, the federal government is currently investigating both ProGen and Cockerell, and Cockerell will likely enter into a settlement with the government in the coming months. In connection with this investigation, Cockerell has spent millions of dollars in attorney’s fees, and has suffered additional financial and reputational harm. Cockerell anticipates that any forthcoming settlement with the government will include payment by Cockerell of millions of dollars. These harms constitute losses and expenses incurred by Cockerell as a result of ProGen’s admitted negligence and misconduct.

224. On July 12, 2017, while the arbitration was pending, the U.S. Attorney’s Office for the Northern District of Texas filed the criminal Felony Information against Erik Bugen, Jody Sheffield, and the Hawrylaks.

225. The Information alleged that the four defendants, and others, conspired to submit fraudulent toxicology and DNA cancer screening tests to TRICARE. The Information named Cockerell Dermatopathology and noted that it “held a CLIA license, which allowed it to perform laboratory tests at its facility and submit claims for those

tests to TRICARE.” The Information alleged that Progen’s lab tests “were the product of kickbacks,” and they were “billed to TRICARE by Cockerell [Dermatopathology].”

226. The Hawrylaks pleaded guilty in August 2017. In their Factual Resumes, the Hawrylaks admitted to conspiring with Bugen, Sheffield, and others to defraud TRICARE. They admitted they provided the ADAR Group with \$10,000 per week to finance, among other things, the purchase of Wal-Mart gift cards to induce TRICARE beneficiaries to provide urine and saliva samples. They also admitted to providing funds to Bugen and Sheffield to pay monthly fees to doctors to sign test forms. Finally, Matthew Hawrylak admitted that urine samples were sent to Progen and billed to TRICARE for unnecessary toxicology and genetic tests.

227. Sheffield and Bugen pleaded guilty in November 2017. In their Factual Resumes, Bugen and Sheffield admitted to conspiring with the Hawrylaks and others to defraud TRICARE. Bugen and Sheffield both admitted that they used \$50 Wal-Mart gift cards to induce TRICARE beneficiaries to provide urine and saliva samples. They both admitted that they paid monthly fees to doctors to sign test requisition forms. Bugen also admitted to obtaining signature stamps from the doctors, and Sheffield admitted to stamping the forms himself. Bugen and Sheffield also admitted to receiving a portion of the reimbursement that TRICARE paid for these fraudulent tests.

228. On or around July 24, 2017, Progen dissolved and forfeited its right to transact business in the state of Texas.

229. On or around August 15, 2017, the Office of Inspector General of the U.S. Department of Health and Human Services issued a subpoena to Progen seeking

information about, among other things, its toxicology and PG testing and its arrangement with CDP.

230. On October 26, 2017, while the CDP arbitration was pending, Quintan filed a Texas state court suit seeking declaratory and injunctive relief against CDP. Quintan claimed he was not subject to arbitration because he only signed the MSA in his representative capacity on behalf of Progen. CDP then filed a counterclaim against the four Progen principals for negligent misrepresentation, negligence, and breach of contract.

231. On December 12, 2018, Progen's four principals were indicted on healthcare fraud charges in connection with the Rxpress pharmacy.

232. At this point, Progen's principals were aware that the government was investigating CDP and Progen. They were aware that CDP had disclosed nearly \$4.2 million in improper tests to TRICARE. They were in litigation against CDP, and they had just been indicted for healthcare fraud related to Rxpress. Progen's principals, like Dr. Cockerell and CDP, knew that millions of dollars would need to be paid back to TRICARE. Progen's principals wanted to resolve their ongoing litigation with Dr. Cockerell and CDP, while also eliminating (or limiting) their exposure to TRICARE. To that end, Progen's principals and CDP negotiated a settlement agreement and memorandum of understanding meant to bring to a close the arbitration and state court litigation, while resolving the outstanding TRICARE issue.

1. CDP expressly warranted that the Progen settlement proceeds would be used to repay TRICARE.

233. In March 2019, CDP executed a Settlement Agreement with Progen, its principals, and its insurance carriers to resolve the arbitration and state court suit. Progen's insurance carriers agreed to pay \$3,485,000 to CDP on behalf of Progen and its principals. The Settlement Agreement was fully executed on March 18, 2019.

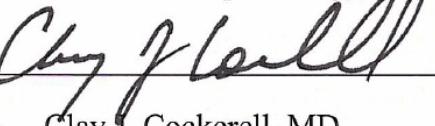
234. Dr. Cockerell signed the Settlement Agreement on behalf of CDP on March 4, 2019.

235. In addition to the Settlement Agreement, CDP and Progen also executed a Memorandum of Understanding explaining the purpose of the settlement payment. CDP specifically "represent[ed] and warrant[ed]" to Progen's principals that the \$3.485 million settlement payment would be used to repay TRICARE, as shown in the excerpt below:

As part of the Lawsuit, CDP seeks payment from the Individuals regarding claims of recoupment and other demands for payment asserted by or on behalf of TriCare against CDP related to ProGen (the "TriCare Claims"). In consideration for, among other things, the Settlement Payment (as defined in the Settlement Agreement), CDP shall use the Settlement Payment to fully repay both (i) the TriCare Claims, and (ii) amounts CDP reasonably believes will be part of the TriCare Claims but are not, as of the date of this Agreement, within the definition of TriCare Claims herein;

236. CDP further represented and warranted that it would "not directly or indirectly persuade or direct TriCare or any other governmental agency ... to seek reimbursement from the [Progen principals] or ProGen for any claims of recoupment." Moreover, CDP agreed that it would not assert that Progen's principals bore any responsibility for any asserted claims of recoupment related to Progen.

237. The MOU was fully executed by CDP, Progen, and its principals on March 8, 2019. Dr. Cockerell signed the MOU as the Owner/President of CDP, shown in the excerpt below:

Cockerell Dermatopathology, P.A.

By: Clay J. Cockerell, MD
Its: Owner/President
Date: 03/08/2019

238. Progen's insurance carriers paid the \$3,485,000 settlement payment after the Settlement Agreement and MOU was signed. On March 29, 2019, CDP and Progen's principals filed an agreed motion dismissing the Texas state court litigation with prejudice. CDP and Progen also dismissed the arbitration.

239. Despite Dr. Cockerell's and CDP's representations and warranties in the MOU, CDP has not paid the \$3,485,000 to TRICARE—nor has it offered to do so. Dr. Cockerell and CDP have knowingly avoided their obligation to repay TRICARE after they received the settlement payment from Progen. In fact, after dismissing the state court litigation, CDP stopped making repayments to TRICARE—even though CDP still owed \$3,607,337.77 for the thousands of improper claims that it had **admitted** in its two retraction letters. CDP's last payment to TRICARE was on March 27, 2019.

240. Despite Dr. Cockerell's and CDP's representations and warranties in the MOU, CDP has attempted to assign blame to Progen and its principals rather than pay the \$3,485,000 Progen settlement to TRICARE.

241. In October 2019, the government issued a civil investigative demand to CDP for, among other documents, “all settlement agreements . . . or memoranda of understanding” related to the Progen litigation. CDP produced the Settlement Agreement to the government on or around February 11, 2020. CDP did not produce the MOU. As of the date of this Complaint, CDP still has not produced the MOU signed by Dr. Cockerell on March 8, 2019 on behalf of CDP in connection with the Progen settlement.

242. Dr. Cockerell and CDP have refused to pay back TRICARE for the fraudulent claims—claims that CDP admitted should not have been submitted in the first place. The government seeks to recover the moneys paid to CDP for the fraudulent Progen claims that CDP knowingly caused to be submitted to TRICARE through its CLIA license. At a minimum, the government seeks to recover the \$3,485,000 Progen payment that CDP wrongfully avoided paying to TRICARE.

FIRST CAUSE OF ACTION

Violations of the False Claims Act:
Submission of False Claims for Payment
31 U.S.C. § 3729(a)(1)(A)

243. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

244. The United States seeks relief against Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. for their violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

245. By virtue of the conduct alleged above, Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. submitted or caused the submission

of thousands of false or fraudulent claims for payment to federal healthcare programs, including TRICARE. Specifically, Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. submitted or caused the submission of fraudulent lab testing services generated by Progen and its marketers.

246. In submitting these claims for payment to federal healthcare programs, Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. certified that the information on the claim forms was true, accurate, and complete, even though they were aware (or recklessly disregarded) that it was not. Defendants' certifications that they were submitting true, accurate, and complete claims was material to the federal healthcare programs' decision to pay for these claims. TRICARE would not have paid for these claims had it known that the claims were not true, accurate, and complete.

247. Defendants' false certifications and representations were made for the purpose of getting false or fraudulent claims paid. Payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendants' statements and actions.

248. Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. submitted or caused the submission of these false claims to the federal healthcare programs, including TRICARE, with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

249. Because of these thousands of false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

SECOND CAUSE OF ACTION
Violations of the False Claims Act:
Conspiracy
31 U.S.C. § 3729(a)(1)(C)

250. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

251. By virtue of the acts described above, Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. conspired and entered into an agreement with Progen and its principals to have the United States pay for false or fraudulent claims. In particular, CDP and Dr. Cockerell agreed that Progen could use CDP's CLIA license and NPI number to submit claims for payment to TRICARE and other federal healthcare programs even though their MSA with Progen specifically prohibited that conduct. CDP accepted payment from TRICARE and other federal healthcare programs, transferred the money to Progen, and solicited and received a cut of the proceeds.

252. Each time CDP transferred money to Progen—money that included TRICARE reimbursement for Progen's testing—was an overt act in furtherance of the unlawful agreement between CDP, Dr. Cockerell, Progen, and its principals. Each time CDP and Dr. Cockerell accepted the Practice Operator payment, knowing that the money included TRICARE and other federal healthcare program reimbursements, was an overt act in furtherance of the unlawful agreement between CDP, Dr. Cockerell, Progen, and its principals. As such, both CDP and Dr. Cockerell agreed and conspired with Progen and its principals to submit false or fraudulent claims for payment to federal healthcare

programs, including TRICARE, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

253. By virtue of the false or fraudulent claims that Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. conspired to be made and/or caused to be made, the United States suffered actual damages in an amount to be determined at trial, and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false or fraudulent claim.

THIRD CAUSE OF ACTION

Violations of the False Claims Act:

Reverse False Claims
31 U.S.C. § 3729(a)(1)(G)

254. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

255. The United States seeks relief against Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. pursuant to 31 U.S.C. § 3729(a)(1)(G).

256. By virtue of the conduct alleged above, Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. knowingly concealed or knowingly and improperly avoided an obligation to pay or transmit money to the United States. Specifically, CDP and Dr. Cockerell represented and warranted that the full \$3,485,000 payment from Progen would be used to reimburse TRICARE for the fraudulent claims that CDP and Dr. Cockerell submitted or caused to be submitted to TRICARE. After receiving payment from Progen, however, CDP and Dr. Cockerell concealed from the

United States the MOU that contained their representations and warranties that the full \$3,485,000 would be used to repay TRICARE. Moreover, CDP and Dr. Cockerell knowingly and improperly avoided their obligation to pay this money to TRICARE.

257. Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. concealed and/or avoided their obligation to pay the United States with actual knowledge of the obligation or with reckless disregard or deliberate ignorance of that obligation.

258. Because of the conduct of Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D., the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation of the reverse False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

FOURTH CAUSE OF ACTION
Unjust Enrichment

259. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

260. The United States asserts a claim under federal common law for recovery of monies by which Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. have been unjustly enriched.

261. By virtue of the conduct and the acts described above, Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D. were unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, should be returned to the United States.

FIFTH CAUSE OF ACTION
Payment by Mistake

262. The United States realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

263. The United States asserts a claim under federal common law for payment by mistake against Defendants Cockerell Dermatopathology, P.A. and Clay J. Cockerell, M.D.

264. By reason the foregoing, the United States made and/or participated in TRICARE payments and other federal healthcare program payments to CDP in reliance on the erroneous belief that CDP and Dr. Cockerell were complying with the Anti-Kickback Statute and the False Claims Act. The erroneous belief was material to the United States' decision to make the payments. Consequently, the United States is entitled to recover the amount of the payments in an amount to be determined at trial.

PRAYER FOR RELIEF AND JURY DEMAND

Accordingly, the United States respectfully requests judgment in its favor as follows:

1. As to the First, Second, and Third Causes of Action of the United States (False Claims Act), statutory damages in an amount to be established at trial, trebled as required by law, and such penalties as required by law;
2. As to the Fourth and Fifth Causes of Action of the United States (Unjust Enrichment and Payment by Mistake), damages to the extent allowed by law;
3. All costs associated with prosecuting this civil action, as provided by law;

4. Interest on all amounts owed to the United States; and
5. All other relief the Court deems just and proper, to be determined at a trial by jury.

The United States demands a jury trial on all claims.

Respectfully submitted this 22nd day of March, 2021:

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